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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/659,983 | 09/10/2003 | Timothy A. Hovanec | P 0284779 081289 | 6073 |

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Pillsbury Winthrop LLP
Intellectual Property Group
Suite 2800
725 So. Figueroa Street
Los Angeles, CA 90017-5406

EXAMINER

MARX, IRENE

ART UNIT PAPER NUMBER

1651

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/659,983 | Applicant(s) HOVANEK, TIMOTHY A. | |
| | Examiner Irene Marx | Art Unit 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-13, 17-19, 22, 23, 32 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-13, 17-19, 22-23 and 32-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The amendment filed 6/15/06 is acknowledged.

Claims 10-13, 17-19, 22-23 and 32-33 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the recitation regarding the isolated nucleic acids of claims 22-23 “wherein the nucleic acid encodes function for oxidizing ammonia to nitrite”. Applicant has not indicated where in the as filed written disclosure the recitation now added finds basis or support. There is no clear indication in the written disclosure that this function is encoded by the 16S rDNA SEQ ID. NO. 18 or by a sequence having 96% identity thereto. That the bacteria containing SEQ ID. NO. 18 oxidize ammonia does not mean that this particular sequence is responsible for encoding the newly asserted function. No clear correlation in this regard is found in the instant written disclosure.

Therefore, this material constitutes new matter and should be deleted.

The rejection under 35 U.S.C 112 regarding deposit is withdrawn in view of the Lu Declaration.

Claims 17, 19, 22 and 32-33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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The specification does not contain any disclosure of the function of all nucleic acid sequences that are 96% identical to SEQ ID NO: 18. The claimed genus of nucleic acids is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated nucleic acids are encompassed within the scope of the claims, including partial nucleic acid sequences. The specification discloses only a single species of the claimed genus, which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Claims 17, 19, 22 and 32-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleic acid of SEQ ID NO: 18, does not reasonably provide enablement for all nucleic acids with at least 96% identity to SEQ ID NO: 18. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQd 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

Claims 17, 19, 22 and 32-33 are so broad as to encompass all nucleic acids with at least 96% identity to SEQ ID NO: 18 and all bacteria including nucleic acids with at least 96% identity to SEQ ID NO: 18. In addition claims 32 and 33 encompass at least two bacterial strains, one of which comprises not only these variants of SEQ ID NO: 18 but also one or more of various variants of SEQ ID NO: 1, 2, 3, 4, 19, 20. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of nucleic acids and bacteria broadly encompassed by the claims. It is noted that SEQ ID NO: 18 encodes a 16S ribosomal subunit. It is known in the art that DNA encoding a bacterial 16S rDNA is used to identify and classify a bacteria isolate. Therefore, SEQ ID NO: 18 is useful for identification of other ammonia oxidizing bacteria (AOB) having a 16S rDNA of

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SEQ ID NO: 18. However, it is unclear as to whether the claimed variants of SEQ ID NO: 18 will be so useful as applicants have not provided guidance as to which of the nucleotides of the nucleic acid of SEQ ID NO: 18 are conserved among AOB. Furthermore, while recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modification, as encompassed by the instant claims, and the positions within a nucleic acid whether modifications can be made with a reasonable expectation of success of identifying other AOB using the claimed variants is limited and the result of such modifications is unpredictable. In addition, one skill in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g., multiple substitutions.

The specification does not support the broad scope of the claims with encompass all nucleic acids with at least 96% identity to SEQ ID NO: 18, bacteria having this sequence or further variants of SEQ ID NO: 1, 2, 3, 4, 19, 20 because the specification does not establish (A) regions of the nucleic acid structure of these various sequences that may be modified without affecting the ability to identify other ammonia-oxidizing bacteria based on the rDNA sequence;

(B) a rational and predictable scheme for modifying any nucleotides of the sequences with an expectation of obtaining the desired biological function, i.e., hybridizing to other AOB rDNA sequences as well as ammonia oxidation capability and

(C) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus applicants have not provided sufficient guidance to enable of the of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including all nucleic acids with at least 96% identity to SEQ ID NO: 18 and bacteria comprising this sequences as well as further bacteria comprising variants of SEQ ID NO: 1, 2, 3, 4, 19, 20. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA) 1970). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skill in the art in unnecessarily, and improperly, extensive and undue. *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988).

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Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicants citation of previously granted patents is not persuasive regarding the prosecution of the present application, since each patent application is prosecuted on its own merits and what was done in a previous case does not constitute imprimatur for the prosecution of further cases. *In re Gyurik*, 596 F.2d 1012, 201 USPQ 552 (CCPA 1979); *In re Attwood*, 267 F.2d 954, 122 USPQ 378 (CCPA 1959); *In re Freedlander*, 136 F.2d 759, 760, 58 USPQ 402, 403 (CCPA 1943).

Applicant did not address the possession aspect of the rejection with any specificity. The recitation of function in this regard is irrelevant, particularly considering that the function now asserted for the sequences *per se* appear incorrect as they pertain to 16S rDNA, or at least find to clear basis in the as-filed specification. Applicant has not shown with any specificity the correlation between the sequences of interest and the alleged function of ammonia oxidation. Moreover, the amendments provided raise issues of new matter.

Therefore the rejections are deemed proper and are adhered to.
No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

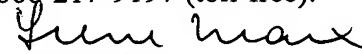
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Irene Marx
Primary Examiner
Art Unit 1651